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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,013

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EXAMINER

KING, FELICIA C

ART UNIT

PAPER NUMBER

1784

MAIL DATE

DELIVERY MODE

09/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,013	Applicant(s) BATEN ET AL.	
	Examiner FELICIA C. KING	Art Unit 1784	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/09; 8/4/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14 and 18 and claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The phrase "fermenting is continued for a time that is longer than the time normally required for optimal growth of the fermenting microorganism" in claims 14 and 18 is relative which renders the claim indefinite. The phrase "fermenting is continued for a time that is longer than the time normally required for optimal growth of the fermenting microorganism" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction, clarification, or cancellation of the claim is required.

4. Claim 16 recites the limitation "the mixture" in line 7 of claim 16. There is insufficient antecedent basis for this limitation in the claim. Claims 17-21 are rejected by their dependency upon claim 16.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. **Claims 15, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Tolton II et al. (US 6,514, 941).**

Regarding Claims 15, 19, and 20: Tolton discloses that beverages and yogurt [col. 5, lines 1-10] can contain a protein hydrolysate that has an angiotensin-I-converting enzyme inhibiting property (ACE or ACEI) [col. 4, lines 63-67; col.5, lines 10-20].

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made

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in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuter (US 3,326,693) in view of Tolton II et al. (US 6,514, 941).

Regarding Claims 10, 11, 12, 13, 15: Reuter discloses mixing casein peptone (hydrolyzed casein) with sterile milk and then inoculating the milk with *Lactobacillus acidophilus* [col. 2, lines 30-49]. Reuter does not disclose preparing a protein hydrolysate that has an angiotensin–I-converting enzyme inhibiting property (ACE or ACEI).

Tolton II discloses preparing a protein hydrolysate that has an angiotensin–I-converting enzyme inhibiting property (ACE or ACEI) and that more specifically the protein hydrolysate is a casein hydrolysate that has C6, C7, and or C12 peptides [col. 2, lines 46-58; col. 3, lines 6-18; col. 4, lines 63-67]. Tolton also discloses that the composition can be used to make beverages and yogurt [col. 5, lines 1-10].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Reuter and Tolton II before him or her to modify the hydrolyzed casein of Reuter for the hydrolyzed casein of Tolton II in order to form a sour milk or a sour milk product that is capable of having an antihypertensive effect. This is especially beneficial for the consumer since foods such as sour milk and its products such as yogurt already provide known health benefits for the digestive tract and immune system.

Further Claim 15 is a product by process claim, “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

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unpatentable even though the prior art was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698. Since there is no evidence that the recited process produces a product that is materially different from what is disclosed in the prior art, claim 15 has been considered regarding its disclosure of beverages and yogurt that can contain a protein hydrolysate that has an angiotensin-I-converting enzyme inhibiting property (ACE or ACEI).

Regarding Claim 14: Reuter discloses fermenting milk with *L. acidophilus* for 12 to 20 hours. Reuter does not disclose that the “fermenting is continued for a time that is longer than the time normally required for optimal growth of the fermenting microorganism” as recited in claim 14.

However, it would have been obvious to modify the fermentation time based on the desired taste or the expression of particular components that are produced by the fermentation process since it has been held that the provision of adjustability, where needed, involves only routine skill in the art, *In re Stevens*, 101 USPQ 284 (CCPA 1954).

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the length of fermentation of the inoculated milk for the production of fermented milk, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

Also see 112 2nd rejection of claim 14.

11. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuyama et al. (EP 1018341) in view of Klaver et al. (US 4,938, 973).

Regarding Claims 16 and 17, 19-21: Masuyama discloses using milk as a starting food material and enzymatically hydrolyzing the starting food material with enzymes that are capable of producing peptides that have angiotensin converting enzyme inhibitory activity [0017, 0018, 0019, 0024]. Masuyama discloses functional foods of the invention being yogurt, acidified milk, or

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fermented sour milk [para 0034]. Although Masuyama discloses the previously recited functional foods, Masuyama does not explicitly disclose that after enzymatically hydrolyzing the milk, fermenting microorganisms are further added to the milk and is then fermented.

Klaver discloses inoculating milk with *Streptococcus thermophilus* or *Lactobacillus bulgaricus* to make yogurt or fermented milk [col. 2, lines 55-67; col.8, lines 47-68, col. 9, lines 9-30]. Klaver also discloses *L. acidophilus* for the production of acidophilus milk [col. 2, lines 20-25].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Masuyama and Klaver before him or her to incorporate or substitute the treated milk of Masuyama, having angiotensin converting enzyme inhibitory activity, for the milk of Klaver in order to provide a fermented food product that has an antihypertensive effect. It would have further been obvious to incorporate or substitute the milk since Masuyama anticipates the use of the treated milk in fermented foods such as yogurt and acidified milk. This is especially beneficial for the consumer since foods such as sour milk and its products such as yogurt already provide known health benefits for the digestive tract and immune system.

Further Claim 19 is a product by process claim, “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698. Since there is no evidence that the recited process produces a product that is materially different from what is disclosed in the prior art, claim 19 has been considered regarding its disclosure of acidified milk, fermented sour milk, and yogurt that have angiotensin-I-converting enzyme inhibiting properties (ACE or ACEI).

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Regarding Claim 18: Masuyama discloses hydrolyzing protein in milk as discussed above. Masuyama does not disclose that “fermenting is continued for a time that is longer than the time normally required for optimal growth of the fermenting microorganism” as recited in claim 18.

Klaver discloses fermenting milk with *Streptococcus thermophilus* or *Lactobacillus bulgaricus* separately for 39 hours [col. 8, Ex. V].

Although Matsuyama and Klaver do not disclose the time for fermentation as recited in claim 18, it would have been obvious to modify fermentation time based on the desired taste or the expression of particular components that are produced by the fermentation process since it has been held that the provision of adjustability, where needed, involves only routine skill in the art, *In re Stevens*, 101 USPQ 284 (CCPA 1954).

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the length of fermentation of the inoculated milk for the production of fermented milk, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

Also see 112 2nd rejection of claim 18.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/F. K./

Examiner, Art Unit 1784

/Timothy M. Speer/

Primary Examiner, Art Unit 1784